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January 4, 2006

Mail Stop Appeal Brief - Patents
Board of Patent Appeals and Interferences
United States Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450

RE: U.S. PATENT APPLICATION SERIAL NO. 10/619,985
FILED JULY 15, 2003
OUR DOCKET NO. N9464-ICW

Dear Sir:

Enclosed for filing are the original and two copies of the Reply Brief for Appellant. You are authorized to charge any deficiency or credit any overpayment associated with the filing of this application to Deposit Account 23-0035.

If you should have any questions, please do not hesitate to contact me.

Very truly yours,

WADDEY & PATTERSON

I.C. Waddey, Jr.
Registration Number 25,180

ICW/sjh
Enclosures

Offices also at:
South Center
100 Clinton Avenue
Suite 302
Montgomery, AL 35801
256.535.4400
Fax: 256.535.4402

Roundabout Plaza • 1600 Division Street • Suite 500 • Nashville, TN 37203
615.242.2400 • Fax: 615.242.2221 • www.iplawgroup.com



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Serial No.:	10/619,985)	
For:	A Device and Method to)	
	Limit Filling of the Heart)	Examiner:
Applicant:	Thomas David Starkey)	Bruce Snow
Filing Date:	July 15, 2003)	
Attorney's Docket No.:	N9464-ICW)	Group Art Unit:
Customer No.:	23456)	3738

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REPLY BRIEF FOR APPELLANT

Appellant respectfully files this Reply Brief to the Examiner's Answer in the above styled matter.

Overview

This is serious business—this inventor has found a way to cure a deadly disease. It is incredulous to suggest that a sandwich bag would obviate this invention. The invention involves a sac of **predetermined** capacity for placement in the chamber of an enlarged heart to limit the pressure on the chamber walls and allow the heart to remodel itself. The Examiner cites no art that functions in this manner to accomplish this result.

Of course, every sac has a limit on the volume it will hold, first to its intended volume, then expanded to the limits of the elasticity of the material from which it is made before it bursts, but that is a mercurial limit. In this case, a “mercurial” limit is not **predetermined**, and certainly none of the art cited by the Examiner discloses a sac with a predetermined volume equal to the amount of blood that would be used to fill the ventricle of a normal size heart. Not one reference cited by the Examiner uses the word “**predetermined**” (or the equivalent thereof) in discussing the volume of the sac that might be disclosed in the reference. In fact, it does not appear that any of the references actually discuss, suggest or address the volume of the sacs that may be disclosed therein. That being the case, how can the Examiner ignore, and more importantly, how could this Board ignore, the limitation of the claims in question that the capacity/volume of the claimed sac is predetermined. That feature of the claimed invention is simply not disclosed, suggested or addressed in the prior art cited by the Examiner.

The Cited References

Looking specifically at the Examiner’s answer, he states that “Noon et al teaches . . . [a] sac being soft and compliant so that it will fill easily with blood to a certain, predetermined volume, but when the sac has reached capacity, no further filling is allowed.” (Examiner’s Answer, pg. 3, 3rd paragraph) Where in the Noon et al patent is there a suggestion of the underlined language? It does not exist. The language of the claim is gratuitously attributed to the reference

by the Examiner without a reference to the column and line of the patent where the alleged teaching or language appears. The reason the citation to column/line is missing is that the teaching is missing from the reference.

The Examiner makes the exact same statement about the Corral et al reference as he makes about the Noon et al reference. (Id. at paragraph 5) Applicant's response is the same as made with respect to the Noon et al reference and is incorporated at this point by reference. The Examiner has simply attributed something to the Corral et al reference that is imagined, not real, and which does not exist. Therefore the rejections based on both the Noon et al and the Corral et al references should be overturned.

The teachings of the Taylor reference are likewise overstated by the Examiner. At page 4 of the Answer, the Examiner states that "Taylor et al teaches a flexible sac 113, 139 . . . having a capacity for receiving a predetermined volume of blood, and said sac, when filled to capacity, appears generally in size and shape to match the size and shape of a ventricle of an undiseased human heart." Where in the patent is the suggestion for the underlined claim language? It does not exist; it is just a gratuitous interpretation by the Examiner, without any suggestion other than the teachings of the disclosure of Applicant's application.

The Examiner's "Response to Argument"

Referring to the Noon et al reference, the Examiner states "There is absolutely no statement made by Noon et al indicating that the sacs can be filled limitlessly" (Examiner's Answer, pg. 5, paragraph 1) (Emphasis in original) The Examiner is experienced enough to know that the test is not whether the reference negates the possibility of a claimed limitation; rather, the reference must positively suggest the limitation in order to deny patentability. See *Verdegaal Bros. v. Union Oil Co. of California*, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987) ("A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference."); *In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1974) (To establish *prima facie* obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art.)

Looking next at the Examiner's response to Applicant's "winded" argument regarding Claim 9 (See, Examiner's Answer, pg. 6, paragraph 2), the Examiner cites language from Noon et al at column 2, lines 61-63 regarding the size and shape of the Noon et al bladders. What the reference is missing, and what is claimed in Claim 9, is the size and shape of the sac when it is filled to capacity. Noon et al does not address the size and shape of his bladders "when they are filled to capacity", therefore the reference does not disclose or suggest the claimed invention. Applicant apologizes for the "winded" argument

regarding this point, but apparently more was needed since the Examiner missed the point.

Next, the Examiner addresses Claim 11. (See, Examiner's Answer, pg. 6, paragraph 3) His argument is contorted and, with all due respect, makes no sense. Does what the Examiner "believes" actually have a bearing on the patentability of Claim 11 without some supporting reference?

Regarding Claim 20 (See, Examiner's Answer, pg. 6, last paragraph), from the Examiner's response, it appears that he does not want to allow the claim, not based on the law, but based on the allegation that the claim is "recklessly broad" and his "belief" (not the teachings of the prior art) that a sandwich bag could be "inserted into a heart chamber and the volume of the plastic from which it is constructed would reduce or limit the volume of blood into said chamber."

The general argument of the Examiner regarding Corral (See, Examiner's Answer, pg. 7, first paragraph) is once again an argument that the reference fails to "negate" the possibility of Applicant's invention. That is not the law. The reference must positively recite or suggest the claimed invention to be the basis of a valid rejection. Corral et al fails to do that, and the Examiner's general argument should be disregarded.

Looking at the Examiner's arguments regarding Claims 8-9 (See, Examiner's Answer, pg. 7, last paragraph), the Examiner indirectly admits that the reference does not teach the sac being the shape of a normal heart chamber. However, not to be deterred, the Examiner recognizes that the sac could be

caused to be so shaped by “folds which would in turn produce blood clots”— exactly what we need to be creating in the heart chamber! To paraphrase Johnny Cochran’s argument in the O.J.Simpson trial, “if the sac don’t fit, you must acquit.” Here, the sac does not have the claimed shape, so the Board must reverse the rejection.

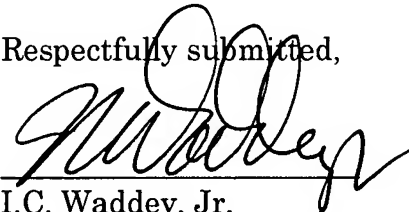
Referring to the Examiner’s argument at the top of page 8 of his Answer addressing the method claims, the raw conclusions of the Examiner are just not supported. The reference does not address the “**predetermined**” capacity of the sac being used in the method, and therefore the claimed language is not met and the rejection must be overturned.

Finally, replying to the argument based on Taylor (See, Examiner’s Answer, pg. 8, last paragraph), the Examiner’s argument does not apply the reference to any claims and therefore cannot be responded to except in the general fashion that Applicant has addressed Taylor et al in the discussion of the references. Applicant does not understand the Examiner’s intent in what appears to be the last sentence of page 8, since it is not in fact a true sentence. With respect to the quote from Taylor at the top of page 9 of the Answer, what is the shape of the member 113 when filled to capacity? Since the reference does not address this question, it cannot be the basis of rejecting claims that claim the size and shape of the sac when filled to capacity.

Conclusion

This invention is the subject of millions of dollars of testing currently being conducted at the University of Michigan. The patent system is intended to reward inventors who contribute significantly to our society. The Board should not condone or validate the rejection of claims where the Examiner has been unable to produce a single reference which in any way discloses, suggests or teaches one of the limitations in the claims. Accordingly, Applicant respectfully requests that the claim rejections be reversed.

Respectfully submitted,

A handwritten signature in black ink, appearing to read 'I.C. Wadley, Jr.', written over a horizontal line.

I.C. Wadley, Jr.
Registration No. 25,180
WADDEY & PATTERSON
A Professional Corporation
Customer No. 23456

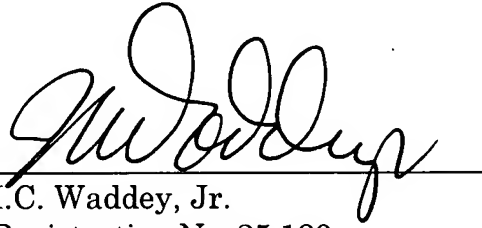
ATTORNEY FOR APPELLANT/APPLICANT

I.C. Wadley, Jr.
Wadley & Patterson, P.C.
1600 Division Street, Suite 500
RoundAbout Plaza
Nashville, TN 37203
(615) 242-2400

Certificate of First Class Mailing

I hereby certify that this REPLY BRIEF FOR APPELLANT in triplicate, Certificate of First Class Mailing (1 page), and self addressed return post card are being deposited on the 4th day of January 2006, with the United States Postal Service as First Class mail in an envelope addressed to:

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I.C. Waddey, Jr.
Registration No. 25,180